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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,790	01/14/2002	Richard A. Rosenbloom	QUIG-1006CIP	3053

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,790	ROSENBLOOM, RICHARD A.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 9, 2003 in Paper No. 10 wherein claims 1, 10, and 17 have been amended and claims 21-37 are cancelled. Currently, claims 1-20 are pending in this application.

Applicant's remarks regarding to some crossed out non-patent literature documents, e.g., downloading from internet, in IDS, have been considered but not found persuasive. Even though those downloading from internet in IDS were considered to be "other information" as Applicant asserts, they are not appropriate for IDS under 37 CFR 1.98, because no name of author and no publication data (e.g., date and page) provided, as indicated in the previous Office Action. 37 CFR 1.98 stating: "Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication".

Applicant's amendment amending claims 1-20 by deleting "preventing", filed January 9, 2003 in Paper No. 10 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of enablement in claims 1-20 because of the recitation "preventing" of record stated in the Office Action dated October 16, 2002 has been fully considered and is found persuasive to remove the particular rejection since the recitation "preventing" has been removed. Therefore, the said rejection is withdrawn.

Applicant's amendment deleting the expressions "non-U.S.P. hydrophilic" and "substantially" in claim 17, filed January 9, 2003 in Paper No. 10 with respect to the rejection of claim 17 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, of record stated in the Office Action dated October 16, 2002 have been fully considered and found persuasive to remove the rejection as to claim 17 since these expressions have been deleted from the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement, for reasons of record stated in the Office Action dated October 16, 2002.

Applicant's remarks with respect to this rejection made under 35 U.S.C. 112 first paragraph have been considered but not found persuasive. The instant specification is seen to be insufficient to satisfy the section 112, first paragraph since it fails to provide an adequate support of the claimed methods of the treatment herein "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention" (emphasis added), as discussed below.

As discussed in the previous Office Action, *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than

outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405, and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphasis added).

Applicant asserts that the recitations, "one or more compounds effective to regulate at least one of cell differentiation and cell proliferation" in claim 1-20, "one or more antioxidants" in claim 1 in particular, "structurally similar derivatives thereof which exhibit antioxidant activity" in claim 4, and "one or more antioxidant enzymes" in claim 6, and "anti-inflammatories" in claim 12. However, the instant specification merely defines, for example, at page 4 line 3-5, "The compound that regulates cell differentiation and/or cell proliferation that may be used in the composition of the present invention may be selected from suitable compounds that have this activity". Thus, as CAFC pointed out in *Eli Lilly* "One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." (see *supra*).

Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Claim 1 in particular reads on employment of any compounds effective to regulate at least one of cell differentiation and cell proliferation in the pharmaceutical methods for treating radiation injury in a human, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having the activity herein suitable to practice the claimed invention. Hence, in addition to the absence of fully recognizing the identity of the members genus herein, one of skill is unable to practice the claimed invention.

Therefore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention absent undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, of record stated in the Office Action dated October 16, 2002.

Applicant's remarks with respect to this rejection made under 35 U.S.C. 112 second paragraph have been considered but not found persuasive. The recitations "one

or more compounds effective to regulate at least one of cell differentiation and cell proliferation" in claim 1-20, "one or more antioxidants" in claim 1, "structurally similar derivatives thereof which exhibit antioxidant activity" in claim 4, and "one or more antioxidant enzymes" in claim 6, and "anti-inflammatories" in claim 12, and "compounds containing selenium" in claim 10 render claims 1-20 indefinite since one of ordinary skill in the art could not interpret the metes and bounds as to the recitations herein. Therefore, the scope of claims is indefinite as to the composition encompassed thereby employed in the claimed methods. as failing to clearly set forth the metes and bounds of the patent protection desired.

Applicant's remarks regarding to the license offered by University of Massachusetts for its method of screening for cancer drugs and other drugs that inhibit or promote cell growth, cell dead or cell differentiation for diseases, have been considered but not found persuasive. *Genentech*, 108 F.3d at 1366, the court states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, equivalent to 6,162,801), and Bissett et al. (of record) and Darr et al. (of record) in view of Shimoi et al. (of record) and Kim et al. (5,776,460, of record), for reasons of record stated in the Office Action dated October 16, 2002.

Applicant's remarks filed January 9, 2003 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant asserts that Kita dose not teach a vitamin D to be administered orally in the claimed method herein in treating radiation injury in a human. Contrary to Applicant's assertion, Kita teaches that "Therapeutic vitamin D is administered orally or by injection, and is applied to the skin as an active vitamin D ointment in the case of skin conditions" (see col.1 lines 42-44 in particular). Kita further teaches that "It is known that the molecular structure of vitamin D is altered in the liver and kidneys, converting it into biologically active vitamin D" (see col.1 lines 44-46 in particular), and "It is now known that there are active vitamin D receptors in the cells, and the inhibition of cell activity is being studied since active vitamin D inhibits the production of a variety of cytokines" (see col.1 lines 63-67). Moreover, Kita teaches that "In general, the ultraviolet (UV) light absorption spectra of vitamin D and active vitamin D have absorption maxima 265 nm, with the molar absorption coefficients of about 18,000". See col.1 lines 25-28. Hence, one of skill in the art would recognize that the molar absorption coefficients of

UV radiation for vitamin D are very high. Therefore, based on the teachings of Kita, one of ordinary skill in the art would have found it obvious to administer a vitamin D orally in treating radiation injury in a human.

Additionally, oral administrations of vitamin D are well-known in the art. Thus, oral administration of vitamin D would inherently treat radiation injury in a human under the doctrine of inherency. See *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001).

Furthermore, as indicated in the previous Office Action, since all active composition components herein are known to useful to treat radiation injury, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

It is noted that the record contains no clear and convincing evidence of nonobviousness or unexpected results for the oral compositions herein employed in the claimed method herein over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
March 11, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER
3/24/03